

CLINICAL ETHICS

The current state of clinical ethics and healthcare ethics committees in Belgium

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Ethics committees are the most important practical instrument of clinical ethics in Belgium and fulfil three tasks: the ethical review of experimental protocols, advising on the ethical aspects of healthcare practice, and ethics consultation. In this article the authors examine the current situation of ethics committees in Belgium from the perspective of clinical ethics. Firstly, the most important steps which thus far have been taken in Belgium are examined. Secondly, recent opinion by the Belgian Advisory Committee on Bioethics with regard to ethics committees is presented and the activities of Belgian ethics committees are discussed. Finally, the option to bring research ethics and clinical ethics under the roof of just one committee is criticised using a pragmatic and a methodological argument. Concomitantly, the authors build an argument in favour of the further development of ethics consultation.

ethics consultation, the integration of the consultation service in the hospital, and the availability of ethics consultation. The common attribute of ethics consultations is their limited scope: the assistance is limited to one specific case in which ethical problems appear.

INTERNAL REGULATIONS

In Belgium, the development of clinical ethics took place in several phases. During the initial phase the establishment of ethics committees was mainly a matter of internal regulation. After some local initiatives, the Belgian Order of Physicians took over the initiative in 1984 by publishing a guideline which stated that, in line with international standards, every research protocol that involved human subjects had to be evaluated by a REC beforehand.

In 1992 the Order of Physicians' National Council published a second guideline on the functioning of ethics committees which significantly extended the role of ethics committees: from then on ethics committees had to provide the space for systematic reflection on the ethical and philosophical aspects of healthcare practice. However, the Order of Physicians at that time did not consider it appropriate to entrust a separate committee with this task: "It is superfluous to enlarge the committees for ethics indefinitely by establishing extraordinary committees for ethical reflection. Thus, members of the ethics committees which are concerned with experiments on humans and with scientific research can participate in ethical reflection [...]"⁴ As a result, Belgian ethics committees had to combine the tasks of both the REC and HEC.

EXTERNAL REGULATIONS

The era of internal regulation of ethics committees ended in 1994 with the Royal Decree of 12 August 1994 that obliged all general and psychiatric hospitals to establish a so-called "local ethics committee". These committees were assigned a guiding and consultative task with regard to the ethical aspects of hospital care and a review task with regard to all protocols concerning human experimentation and reproductive human material. By law, the existing ethics committees also acquired the task to perform ethics consultations; the full ethics committee, or one or more members of the committee, would then provide support for

Clinical ethics is characterised by an essentially practical orientation: identifying, analysing, and solving ethical problems that arise in the daily healthcare practice.¹ To achieve this objective two instruments have been developed and implemented in recent years: healthcare ethics committees and ethics consultation. Healthcare ethics committees or hospital ethics committees (HECs) interpret relevant practical experiences out of the clinical setting in a normative way and provide ethical orientations that can lead to the achievement of optimum healthcare.² The task of HECs therefore consists of orientating and supporting healthcare workers in dealing with the ethical aspects of healthcare practice. HECs should be distinguished from research ethics committees (RECs) or, in the United States, institutional review boards (IRBs) which review the protocols of human experimentation by verifying whether the rights, safety, and wellbeing of participating subjects are protected. More general ethical problems linked to clinical tests are not considered part of the REC's tasks.

Ethics consultation is a second practical instrument of clinical ethics and concerns the patient related activity of clinical ethics whereby healthcare workers, patients, and their family are supported in identifying, analysing, and solving ethical conflicts which arise in the clinical setting.³ Different models of ethics consultation exist according to the eligibility for requesting an

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healthcare workers who have to deal with ethically problematic cases.

In 2000 the Belgian Court of Arbitration, established to deal with conflicts of competence in the federal state, overruled this threefold task with its judgement of 31 October 2000 (No 108/2000) that stated that the Belgian federal lawmaker did not have the authority to set ethics consultation as one of the tasks for ethics committees because the competence to legislate on person related issues in healthcare resides with the regional authorities. Through this decision, ethics consultation no longer applies to Belgian ethics committees. The annual activity report of 2001 however indicates that the ethics committees did not refrain from carrying out ethics consultations, despite the ruling.

The Royal Decree of 12 August 1994 also governs the composition of ethics committees. According to the decree, every committee has to consist of at least eight and at most 15 members, the membership of the committee has to represent both sexes, and the majority of members must be associated with the hospital as physicians. It is also obligatory for every committee to contain a lawyer, a nurse, and a general practitioner who is not associated with a hospital. The law further allows for other interested parties to participate as members of the committee. Lastly, the membership of the ethics committee is not only limited in numbers but also by function. The director of the healthcare institution, the chief physician, the chairman of the Medical Council, and the chief nurse are not allowed to sit on the committee.

RECENT GUIDELINE OF THE BELGIAN FEDERAL ADVISORY COMMITTEE ON BIOETHICS

Recently, the Federal Advisory Committee for Bioethics issued a new opinion on ethics committees in which the Committee makes recommendations on the recognition criterion, composition, and functioning of ethics committees. In this opinion the Committee focuses on the harmonisation of Belgian legislation with the EU Good Clinical Practice Directive, which came into force on 1 May 2004.⁵ The changes proposed in the Advisory Committee's opinion are therefore primarily of a formal character (for example, composition, annual capacity, and know how of the committee) in order to ensure good clinical practice through adequate ethical review of research protocols, as envisaged by the European Guideline Good Clinical Practice.

The guideline of the Federal Advisory Committee for Bioethics, however, contains two interesting paragraphs with regard to clinical ethics. Firstly, the guideline proposes a change in the composition of the committees: from now on every ethics committee will have to include a philosopher or a representative of the humanities authorised to speak on medical ethics. A philosopher or representative of the humanities could play an important role in countering the formalisation of the ethical discussion, which could occur when an inflationary wave of legal stipulations and formal conditions, such as good clinical practice guidelines, starts to dominate and steer the ethical discussion. In a previous guideline the Advisory Committee already stated that this formalisation could lead to a "de-moralisation" of the ethical discussion, whereby the ethical reflection has to give way to conformism to procedures.⁶

Despite the fact that the Advisory Committee's opinion mainly focuses on the review of experimental protocols, it stresses secondly that the ethics committees in Belgium are deemed to perform other tasks as well, referring to the guidance function and ethics consultation. No further recommendations, however, are made to optimise the efficacy of clinical ethics as embodied by the ethics committees.

Table 1 Committee activity of ethics committees in Belgium, 1998–2001⁸

	Ethics			
	Protocol review	Guidance	consultation	Not specified
1998	87%	9%	3%	1%
1999	86%	10%	3%	1%
2000	90%	7%	2.5%	0.5%
2001	90%	7%	2%	1%

ACTIVITIES OF ETHICS COMMITTEES IN BELGIUM

Information on the functioning of the ethics committees in Belgium is restricted to an annual report of the Advisory Committee on Bioethics in which the data of the individual activity reports of the ethics committees are presented. Since 1998 the Advisory Committee requests all Belgian ethics committees to supply a dossier of every activity they perform. The collection of these dossiers together with a report on the structure of the committee constitutes the activity report of every individual committee.⁷

These annual activity reports indicate that the review of experimental protocols largely outruns the other tasks (see table 1) while the ethics committees only spend 7–10% of their time to perform the tasks of a healthcare ethics committee. In specialised hospitals the guidance task is noticeably more important than in general hospitals; in geriatric hospitals the share of the clinical ethics related tasks overrules the review function. For all ethics committees, 2–3% of the committee's activity concerns ethics consultation.

Concerning the representativeness of these data, two remarks have to be made. First it is important to acknowledge that until now ethics committees are not obliged to participate in the questionnaire. This voluntariness makes the accuracy of the annual report to a large extent dependent upon the willingness of the committees to participate in the reporting. In recent years a negative trend in reporting the committees' activities is noticeable. From a response rate of almost one in two (49%) for the first annual activity report the response rate dropped to less than 40% in the year 2001.⁸ A plausible explanation for this low level of response is the current lack of financial and administrative support for ethics committees.

A second problem concerning the representativeness of the data is the insufficient availability of parameters, such as information on the geographical location and the religious background of the hospitals that responded to the questionnaire, in order to determine the generalisability of the data. The data are therefore only a vague indicator of the factual activities of the ethics committees in Belgium.

Despite these inadequacies the annual activity reports clearly indicate the supremacy of the review task over the guiding and supporting tasks, a trend that has also been confirmed by a qualitative study of 15 ethics committees.⁹

CRITICAL REMARKS

The multiple tasks of the ethics committees

By combining the tasks of HECs and RECs, the Belgian ethics committees have been set a broad task which in other countries is entrusted to different committees, in line with the existing international consensus that it is unfavourable to bring research ethics and clinical ethics under one roof.¹⁰ Apart from Italy, all other European countries have split research ethics and clinical ethics and handed those to various committees; in Belgium, too, some committees have on their own initiative separated themselves into an HEC and an REC because the combination of the two risks disrupting

the committee's performance.^{11 12} In the US, too, research ethics and clinical ethics are strictly separated: IRBs, whether or not regionally organised, fulfil the review task, whereas HECs perform the guiding task and run the clinical ethics consultation.

Three factors explain the current Belgian situation where protocol review overburdens the work of ethics committees so that clinical ethics risks being compromised. Firstly, it must be noted that the much stronger development of the review task is a general trend which can be discerned in other countries too.¹³

Secondly, in Belgium a historical factor is at work: ethics committees already operated for several years as review committees before they were confronted with the guideline of the Order of Physicians in 1992 and with the new legal framework for committees in 1994, which both proposed a broader task for the ethics committees. After a legal framework for the functioning of ethics committees was established in 1994, committees formally adapted to this new situation by extending the description of their task, without however following up on this immediately in practice.⁹ They therefore remained, as originally intended, as review committees and accepted pro forma the clinical ethics related tasks as well.

A third factor that explains the dominance of the review task in Belgium is the difference between the obligation to review and the obligation to offer guidance by formulating opinions and conducting ethics consultations. Ethics committees are indirectly obliged to perform the review function. The protocol of an experimental research project has to be assessed by an ethics committee before the research may proceed. Moreover, the Advisory Committee on Bioethics proposes in its latest opinion the introduction of a minimum threshold of 20 review tasks annually, as one of the recognition criteria for ethics committees. When committees do not achieve this minimum number of reviews they can either join another committee or lose their legal recognition. No obligation, however, is applicable in the fulfilment of guiding and/or ethics consultation; the guiding task is only described as one of the "possible" tasks of a local ethics committee, without mentioning any specific obligation. This makes the clinical-ethical function entirely dependent upon the ethical dynamism of the hospital or the proactive attitude of members of the ethics committee.

From the viewpoint of strengthening clinical ethics, both a pragmatic and a methodological argument can be formulated in favour of systematically separating research ethics and clinical ethics related tasks. The pragmatic argument is as follows: *by separating research ethics and clinical ethics related tasks, the dominance of the review task will be neutralised and more room will be created for clinical ethics.* At present, the review of research protocols dominates the other two clinical-ethical functions of committees. This dominant position of the review task can be clarified through three factors which are at work here.

Alongside this pragmatic argument, a methodological argument also exists in favour of a separation of research ethics and clinical ethics related tasks: *the object, required expertise, and substantial aspects of the review task differ to such an extent from those of the guiding and supporting tasks that it is not desirable to entrust the review task as well as the guiding and supporting tasks to just one committee.*

There is a clearly discernible difference between the review and guiding tasks with regard to the object of ethical review and reflection. Next to the scientific and legal evaluation of a research protocol, the review task concerns the ethical review, whereas the clinical ethics related tasks are exclusively concerned with the ethical aspects of healthcare practice and individual cases involving difficult ethical problems. The

required expertise to ethically assess research protocols in an adequate way concerns first and foremost expertise in clinical research. The Advisory Committee on Bioethics is therefore right to emphasise in its latest guidance that specific training should be provided for in the methodology of clinical research.¹⁴ Research ethics regards content based upon international agreements such as the Declaration of Helsinki, that depart from human dignity, the protection of subjects of research, and the medical scientist's responsibility towards society. These declarations formulate an "ethical minimum" to which clinical research has to adhere before the research can be executed. Clinical ethics goes beyond the point where the ethics of biomedical research stops; the guidelines that embody the "ethical minimum" of research ethics constitute for clinical ethics the "minimum minimum" on the basis of which the relationship between the healthcare worker and the patient can be further developed towards "the most humanely possible".¹⁵ This substantial difference between research ethics and clinical ethics reflects the difference between the obligations of a medical researcher with regard to human subjects who participate in experimental research and the obligations of a doctor to his patient.¹⁶

Ethics consultation

According to the legal framework established in 1994, ethics committees also carry a responsibility for ethics consultation. It shows from the available activity reports of the Belgian ethics committees that this ethics consultation plays only a limited role in the activities of the committees. Moreover, since the Court of Arbitration's ruling of 2000 this task operates in a legal vacuum.

The theme of ethics consultation is however not "terra incognita" in Belgium. In the early 1990s the question was posed how clinical-ethical casuistics could be developed and how this should relate to the ethics committees.¹⁷ Over time, a partial answer to these questions has been formulated specifically in the Belgian debate on euthanasia, by the proposal of the Advisory Committee to engage in an ethics consult when a patient had opted for euthanasia.

The idea of an ethics consult is mentioned for the first time in "Opinion No 1 concerning the desirability of a legal regulation of euthanasia" which was developed by the then newly established Belgian Federal Advisory Committee on Bioethics in 1997 and which had to identify the various possibilities of legislating on euthanasia.¹⁸ The proposal concerns an obligatory consultation with an independent ethicist (non-physician) who is appointed by the ethics committee and who, before actions are taken to end life, judges ethically the euthanasia request of the patient in consultation with the healthcare team and the family.

A consequential argument could however be made in favour of a further extension of ethics consults: *the availability of ethics consultation results in an optimisation of patient care.* Evidence exists that the availability of ethics consultation leads to optimised patient care. Recent prospective research of Schneiderman *et al* (executed during the period from late 2000 until late 2002 in seven American hospitals on the impact of ethics consultation on the department of intensive care) found that for patients on whose condition a clinical-ethical discussion was in place, the number of hospital days as well as the duration of life lengthening treatment were reduced.¹⁹

In order to achieve adequate ethics consultation coordinated action is necessary, especially as regards the institutional framework in which ethics consultation has to operate. The possible options are situated between two opposite models: complete integration of ethics consultation with the ethics committee on the one hand, and the independent

functioning of an ethics consultation service on the other hand. Here, an argument can be made in favour of associating the ethics consultation service and the ethics committee within the healthcare institution: *the avoidance of the focus on the immediate and the particular*. Through its focus on particular cases, clinical ethics risks to promote short term thinking while structural elements that give rise to certain ethical problems fall beyond the scope of the ethics consultation.²⁰ In actual practice, the limited scope of ethics consultations is often implicitly remedied by the additional assignments of the ethics consultants; they are also active in teaching, training, and policy making. However by institutionally associating the ethics consultation service and the ethics committee, the exchange of information flow between the consultation service and the committee will be assured. The ethics committee will then be able to identify more rapidly the structural problems that underlie the ethical problems for which ethics consultations are requested. By doing so, the ethics committee and the ethics consultation service will engage in complementary activities that obviate the inherent myopia of the ethics consultation service on the one hand and integrate the ethics committee more fully in the clinical practice of the healthcare institution on the other hand.

CONCLUSION

The instruments that embody clinical ethics in practice that thus far have been developed in Belgium provide a first step in the establishment of clinical ethics and the realisation of optimised patient care. Available data show that the functioning of ethics committees is dominated by the obligation to review protocols of human experimentation, which is to the detriment of the clinical ethics related tasks, particularly the guidance task and ethics consultation. In this paper we have argued in favour of the institutional separation of research ethics and clinical ethics, and also for the further development of ethics consultation.

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